Q&A | GENOSURE ARCHIVE™

1. **What is GenoSure Archive™?**
   A: GenoSure Archive is designed to provide HIV-1 antiretroviral (ARV) drug resistance data when a patient’s viral load is suppressed or too low for standard resistance testing. The assay interrogates the viral archive using next-generation sequencing (NGS) to provide a list of the archived mutations and assigns susceptibility calls of **sensitive**, **resistant**, or **resistance possible** based on those mutations.

   The assay provides susceptibility data for four classes of ARV drugs, including nucleoside/tide (NRTIs) and non-nucleoside (NNRTIs) reverse transcriptase inhibitors, protease inhibitors (PIs), and integrase inhibitors (INIs) — all in one assay.

2. **How is GenoSure Archive different from GenoSure MG or GenoSure PRIme?**
   A: The GenoSure Archive assay is a suppression management tool, specifically designed for use with patients who are virologically suppressed. GenoSure MG and GenoSure PRIme are appropriate for resistance testing when a patient’s virus replication is not controlled and the viral load is ≥500 copies/mL. GenoSure Archive sequences cell-associated DNA, while GenoSure MG and GenoSure PRIme sequence actively replicating plasma virus in those patients with HIV-1 viral loads ≥500 copies/mL.

   GenoSure Archive and GenoSure PRIme both provide susceptibility information for NRTIs, NNRTIs, PIs, and INIs. GenoSure MG provides susceptibility info for NRTIs, NNRTIs, and PIs.

3. **What are the features of GenoSure Archive?**
   A: GenoSure Archive features include:
   - Evaluation of the nucleotide sequence of the HIV-1 polymerase (pol) gene, including the full-length protease and integrase coding regions and amino acids 1-400 of reverse transcriptase.
   - Use of Monogram’s proprietary HIV-1 genotypic interpretation database for HIV-1 protease and reverse transcriptase, which is comprised of more than 100,000 matched genotype-phenotype results, and Monogram’s proprietary HIV-1 genotypic database for integrase.

4. **What is the turnaround time for GenoSure Archive?**
   A: The results of the assay are typically available approximately 10 days after receipt of a sample at Monogram Biosciences.

5. **Has GenoSure Archive been validated?**
   A: GenoSure Archive has been validated in accordance with CAP/CLIA specifications in Monogram’s CAP/CLIA accredited clinical reference laboratory in South San Francisco, Calif.

6. **What are the specimen requirements for GenoSure Archive?**
   A: One 4 mL lavender top (EDTA) tube of whole blood. Do **Not** centrifuge. Freeze immediately at -20°C and ship fully frozen on dry ice.

7. **If my patient has a viral load ≥500 copies/mL, can I still use GenoSure Archive?**
   A: Although GenoSure Archive results may be obtained in all patients regardless of viral load, it is intended to provide information about the viral archive, not actively replicating virus. Replicating virus is the most current form of the virus, and thus GenoSure PRIme or GenoSure MG are the more appropriate genotypic assays for patients with viral loads ≥500 copies/mL. It is more appropriate to use GenoSure Archive when standard resistance testing might not be feasible due to undetectable plasma viral load or viral load levels that are too low for standard resistance testing.
8. **Which patients may benefit from GenoSure Archive?**
   
   **A:** GenoSure Archive is designed to provide HIV-1 ARV drug susceptibility data when standard resistance testing cannot be performed due to inadequate plasma viral load. This assay may provide a useful tool in suppression management, specifically to aid in regimen switches or simplification. The assay may also benefit patients for whom treatment and resistance history is not available.

9. **My patient is naïve to integrase inhibitors. Instead of GenoSure Archive, is there a proviral DNA assay that includes information only for the protease and reverse transcriptase inhibitors?**
   
   **A:** Yes. HIV-1 DNA Sequencing Protease-Reverse Transcriptase (LabCorp 551730, Monogram R6010) is available for integrase inhibitor treatment-naïve patients with low or undetectable viral loads. Also available is HIV-1 DNA Sequencing Integrase (LabCorp 551965, Monogram R6020), which provides susceptibility information for integrase inhibitors only.

10. **How is the genetic sequencing performed for GenoSure Archive?**
    
    **A:** The viral DNA segments isolated from infected cells in whole blood samples are sequenced using NGS methods. NGS employs techniques to sequence the DNA across millions of reactions in a massively parallel fashion. This allows for quantitative, highly sensitive and rapid sequencing of large stretches of DNA.

11. **Is GenoSure Archive appropriate for use in detection of drug resistance for patients infected with HIV-2?**
    
    **A:** No. GenoSure Archive was designed and validated for use only in patients infected with HIV-1.

12. **Is GenoSure Archive covered by insurance?**
    
    **A:** The CPT codes for this assay are 87900, 87901, and 87906. Coverage and reimbursement may vary based on individual insurance plans, including deductibles and/or copays. Please contact the patient's insurance carrier for specifics.

13. **What if my patient does not have insurance coverage?**
    
    **A:** Monogram has established Gateway, a patient assistance program for low income, uninsured patients. For details, please call Monogram's Gateway line at 877-436-6243.

14. **How do I order GenoSure Archive?**
    
    **A:** GenoSure Archive is available as a standalone assay: LabCorp test number: 551776 and Monogram test number: R6000.

15. **How often are the GenoSure Archive resistance mutations and the susceptibility interpretation database updated?**
    
    **A:** The interpretation database and relevant resistance-associated substitutions are updated as new data emerge.

16. **Where can I learn more about GenoSure Archive?**
    
    **A:** Monogram's client services group is available to answer questions. Call 800-777-0177 or visit our website at www.monogrambio.com. Our medical science liaison team is also available to address questions about GenoSure Archive and can be contacted through our client services group.

---

**References**


---

*All descriptions herein also apply to HIV-1 DNA Sequencing Protease-Reverse Transcriptase. HIV-1 DNA Sequencing Protease–Reverse Transcriptase provides susceptibility data for nucleosides/tides, nonnucleosides and protease inhibitors. HIV-1 DNA Sequencing Integrase provides susceptibility data for integrase inhibitors.*